UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

MERCK SHARP & DOHME :

PHARMACEUTICALS SRL, : Civil Action No. 07-1596 (GEB)

:

Plaintiff,

:

v. :

TEVA PHARMACEUTICALS USA, et al.

MEMORANDUM

Defendants. : OPINION

HUGHES, U.S.M.J.

This matter comes before the Court on Motion by Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively, "Teva" or "Defendants) to Compel Production of all privileged communications concerning Plaintiff's allegedly fraudulent conduct in obtaining the '473 patent [dkt. entry no. 32], returnable October 6, 2008. Plaintiff Merck Sharp & Dohme Pharmaceuticals SRL ("MSD" or "Plaintiff") opposed the Motion on October 2, 2008. Defendants filed a reply brief on October 16, 2008. The Court heard oral argument on October 22, 2008 that included a PowerPoint presentation by Defendants. At the request of the Court, the Plaintiff and the Defendants each submitted supplemental memorandum addressing the intent and materiality elements of the crime-fraud exception on October 29, 2008. Plaintiff submitted a letter in response to the Court's October 22, 2008 request for *in camera* review of certain privileged documents on October 29, 2008. For the reasons stated herein, Defendants' Motion to Compel is denied and Defendants' Motion for alternative relief is denied as moot.

I. BACKGROUND AND PROCEDURAL HISTORY

This litigation arises from MSD's allegation that Teva committed an act of infringement on the '473 patent under 35 U.S.C. § 271(e)(2)(A). See Pl.'s Comp. at 5. Teva contends that MSD acquired the patent-in-suit by fraudulently concealing material prior art from the United States Patent and Trademark Office ("PTO"). (Defs.' Br. at 1.) Specifically, Teva claims that "MSD misled the PTO into believing that the prior art did not suggest the allegedly novel and non-obvious feature of the compounds claimed in the '473 patent." *Id.* at 2. Teva explains that "[t]hat feature is the presence of a tertiary alcohol at the O² position of the compounds claimed in the '473 patent [and] . . . this very feature was suggested by two prior art publications by an MSD scientist, Dr. Young . . . [but, was not disclosed] to the PTO." Id. MSD contends that "[t]he two articles disclosed a basic, abstract hypothesis as to some possible features of LTD4 receptors, which, in actual living systems, including humans, are extremely complex three-dimensional structures." (Pl.'s Opp'n Br. at 1.) MSD maintains that its "decision that the two articles were not material to the development of better LTD4 antagonists, evidenced by its decision to publish the two articles, demonstrates that Merck and its employees could not have had any intention of deceiving the PTO." *Id.* at 1-2.

On September 8, 2008, Plaintiff filed the present Motion to Compel Production of all privileged communications concerning Plaintiff's allegedly fraudulent conduct in obtaining the '473 patent. On October 2, 2008, the Motion was opposed.

A. Defendants' Arguments in Support of the Motion to Compel

Defendants make two arguments why the Motion to Compel should be granted.

Specifically, Defendants argue that they are "entitled to this relief (1) pursuant to the crime-fraud

exception to the attorney-client privilege; and (2) because MSD has waived the privilege by injecting into issue the alleged good faith state of mind of those involved in the prosecution of the '473 patent." (Defs.' Br. at 1.) Further, Defendants argue that "[a]lternatively, if the Court concludes that there has been no waiver, then those involved in the prosecution of the '473 patent should be precluded from testifying about their alleged good faith state of mind." *Id*.

Teva asserts that, "[t]he attorney-client privilege does not extend to communications made for the purpose of getting advice for the commission of a fraud or crime." (Defs.' Br. at 15) (citing *Bumgarner v. Hart*, No. 05-3900, 2007 WL 38700, at *3 (D.N.J. Jan. 4, 2007)). Teva also asserts that a *prima facie* case of common law fraud is established through their showing of "(1) a misrepresentation or concealment of a material fact, (2) an intent to deceive or, at least, a state of mind so reckless as to the consequences that it is held to be the equivalent of intent (scienter), (3) a justifiable reliance upon the misrepresentation or concealment by the party deceived which induces [it] to act thereon, and (4) injury to the party deceived as a result of [its] reliance." *Id.* at 15-16. (quoting *For Your Ease Only, Inc. v. Calgon Carbon Corp.*, No. 02 C 7345, 2003 WL 22889442, at *1 (N.D. Ill. Dec. 5, 2003)) (citations omitted).

Teva argues that "[t]he Young LTD₄ receptor model was the road map that promptly directed Belley to the allegedly non-obvious tertiary alcohol [and] [n]othing could be more material than the prior art that suggested the allegedly non-obvious feature of the alleged invention." *Id.* at 17. Teva also argues that "[c]ertainly, a reasonable examiner would have found this information important in deciding whether to allow the claims of the '473 patent . . . [because] the undisclosed Young LTD₄ receptor model reveals that the tertiary alcohol was far from non-obvious, but rather it was a 'likely modification,' as confirmed by inventor Labelle"

Id. at 17-21. Teva further argues that those involved in the instant patent prosecution should have known that the LTD4 receptor model was material and "[t]he withholding of the Young LTD4 receptor model also allowed MSD to mislead the PTO into believing that there was no prior art suggestion to use a tertiary alcohol at the Q2 position." Id. at 17. Lastly, Teva contends that at the very least, the Court should conduct an in camera review of the withheld materials because "[t]he extraordinarily high materiality of the withheld Young LTD4 receptor model, combined with MSD's inability to explain why this information was not disclosed to the PTO, is more than sufficient to cause a reasonable person to have a good faith belief that a review of MSD's privileged communications may reveal additional evidence of MSD's fraud in connection with the non-disclosure of this prior art." Id. at 22. Therefore, if Teva's Motion to Compel is not granted under the crime-fraud exception, Teva requests the Court to conduct a review of all documents that refer or relate to the LTD4 receptor model, the Young publications, their materiality, and the circumstances of MSD's non-disclosure. Id.

Next, Teva argues that "[f]airness prevents a party from disclosing facts beneficial to its position while refusing to disclose, on the grounds of privilege, related facts adverse to its position." (Defs.' Br. at 22) (quoting *General Electric Co. v. Hoechst Celanese Corp.*, No. 87-458, 1990 U.S. Dist. LEXIS 14106, at *22.) Teva asserts that "[i]n an effort to establish a pretext of good faith, several of MSD's witnesses testified that they cannot recall whether they were aware of the Young LTD₄ receptor model during the prosecution of the '473 patent [and] [t]hese witnesses offered this testimony without objection by MSD." *Id.* at 23. Teva also asserts that "[MSD] will attempt to argue that these witnesses could not have disclosed to the PTO what they may have not recalled at the relevant time." *Id.* Teva further asserts that "it would be manifestly

unfair for MSD to rely on the supposed good faith state of mind of those involved in the prosecution of the '473 patent while simultaneously hiding behind the privilege and withholding communications that reveal otherwise." *Id.* at 23-24.

Moreover, Teva cites two cases in support of its proposition that fairness mandates that MSD has waived the attorney-client privilege. "In *General Electric*, the patentee attempted to establish its alleged good faith in connection with the non-disclosure of certain experiments to the PTO by relying on the testimony of the two inventors who claimed that they did not recall the experiments during the prosecution of the patent in suit." *Id.* at 24. Teva emphasizes that "[i]n ordering the production of the privileged communications, the court aptly noted that '[t]he only way for defendants to refute these assertions [e.g., lack of awareness of the experiments] is to examine the privileged communications' regarding the inventors' knowledge of the experiments." *Id.* (quoting *Gen. Elec.*, 1990 U.S. Dist. LEXIS, at *25.) "Similarly, in *Starsight Telecast*, the court found a waiver of the attorney-client privilege where the patentee attempted to establish its good faith by claiming a lack of knowledge of the undisclosed prior art." *Id.* (citing *Starsight Telecast*, 158 F.R.D. 650, 654 (N.D. Cal. 1994)).

Ultimately, Teva asserts that the Court should grant their Motion to Compel or alternatively, "MSD should be precluded from offering alleged good faith explanations from those involved in the prosecution of the '473 patent for their non-disclosure of the Young LTD₄ receptor model." *Id.* at 26.

B. Plaintiff's Arguments Opposing the Motion to Compel

In opposition, Plaintiff argue s that Teva's crime-fraud claim fails because Teva has not, and cannot prove the elements of the crime-fraud exception to the attorney-client privilege. (Pl.'s

Opp'n Br. at 2.) Plaintiff also argues that Teva's arguments on waiver of the attorney-client privilege fail because Teva failed to cite and apply controlling law. *Id*.

With regards to Defendants' crime-fraud claim, MSD asserts that "[b]ecause Teva has not, and cannot, set forth evidence establishing inequitable conduct, its crime- fraud claim must fail because the materiality and deceptive intent required for inequitable conduct are also elements of the crime- fraud exception." Id. at 2. MSD asserts that Teva has not established the materiality element of the crime-fraud exception because "[t]he abstract LTD4 receptor model disclosed in the Young publications conveyed no information to one of skill in the art beyond that gleaned from prior art compounds." *Id.* at 8. MSD also asserts that "[t]he patent-in-suit covers compounds that have a tertiary alcohol on the end of the Q² side chain [and] [t]ertiary alcohols are among the thousands, if not millions, of possible chemical structures that arguably fit the two-dimensional conceptualized model's criteria." Id. at 10. MSD further asserts that "Teva fails to point out that the conceptualized LTD4 receptor model in no way indicates which, if any, of the myriad of possible chemical groups that meet all of the conceptualized model's criteria are optimal for the end of the Q² side chain . . . [nor] does [it] steer one of ordinary skill in the art to a tertiary alcohol." *Id.* at 11. MSD emphasizes that "[t]he record, when examined in its totality, is clear: one of the most important and unexpected discoveries of this invention is the use of a tertiary alcohol on the end of the Q² side chain [because] [i]t was not obvious given the state of the art at the time of the invention." *Id.* at 13.

MSD argues that Teva has the burden of proving intent, but has failed to offer evidence of any deceptive intent other than that MSD has not proven a lack of intent. *Id.* at 19. MSD also argues that the fact that Merck in-house counsel, Gabriel Lopez reviewed and approved the

Young manuscripts for publication "is evidence that Mr. Lopez did not view the Young publications, and the receptor model disclosed in them, as material to the application for the '473 patent." *Id.* at 20. MSD further argues that "in addition to authoring the two publications that are the basis of Teva's inequitable conduct defense, [Dr. Young] presented the conceptualized "model" at a conference in Tapei that was attended by many of Merck's competitors in the race to develop commercial LTD₄ antagonists." *Id.* at 21. "Thus, [MSD asserts that] Teva's argument is based upon the untenable proposition that Merck intentionally withheld prior art references that disclosed the conceptualized LTD₄ receptor model after Merck had already decided that the information reflected in the model was innocuous enough to share with its direct competitors." *Id.*

MSD argues that Teva fails to provide evidence that the PTO would not have issued the patent-in-suit had the Young publications been disclosed. *Id.* at 23-24. MSD contends that Teva has not cited a single page of the more than 800 pages of prosecution history of the patent-in-suit nor any facts outside the prosecution history to support its contention that without MSD's non-disclosure the PTO would not have granted the patent-in-suit. *Id.* at 24. Further, Teva fails to discuss any injury resulting from the alleged detrimental reliance of the PTO. *Id.* at 25.

Ultimately, MSD maintains that Teva bears the burden of proof on crime-fraud and asserts that "[i]t simply cannot be the case that Teva can prove the serious accusation of fraud with only conclusory, unsupported facts, and without addressing all of the required elements." *Id.* For the same reasons, specifically, the failure of Teva to establish any of the four elements of the crime-fraud exception to the attorney-client privilege, an *in camera* review of the sought documents is not justified. *Id.*

Lastly, MSD argues that Teva's arguments on waiver of the attorney-client privilege fail primarily because Teva does not cite precedent from the Third Circuit to support its waiver argument. Id. at 26. MSD points out that "the Third Circuit expressly rejected the 'liberal' approach to waiver that is set forth in General Electric Co. v. Hoescht Celanese Corp., 1990 U.S. Dist. Lexis 14106 (D. Del. May 8, 1990), and the other cases cited by Teva." Id.(citing Rhone-Poulenc Rorer Inc. v. Home Indemnity Co., 32 F.3d 851, 863-64 (3d Cir. 1994)) ("A party does not lose the privilege to protect attorney-client communications from disclosure in discovery when his or her state of mind is put in issue" even if the information is "vital, highly probative, directly relevant or even go[es] to the heart of an issue."). MSD explains that "[i]nstead, the Third Circuit adopted a more traditional approach to waiver: waiver only results when a party 'attempts to prove a claim or defense by disclosing or describing an attorney client communication . . . and that remains the case even if one might conclude the facts to be disclosed are vital, highly probative, directly relevant, or even go to the heart of an issue." Id. (citing Rhone-Poulenc, 32 F.3d at 863-64). MSD contends that "Merck has not relied on any attorneyclient privileged communication to support its positions in this lawsuit[,] [b]ut, in each of the cases Teva cites in its Motion, there was an actual attorney-client privileged communication that was relied on by the waiving party." Id. at 27. Finally, MSD concludes that the Court should find no waiver because "Teva has wholly failed to prove that Merck has waived the attorneyclient privilege, and has cited no authority whatsoever to support its contention that Merck's trial witnesses should be precluded from testifying on their state of mind." *Id.* at 29.

II. DISCUSSION

A. Federal Rule of Civil Procedure 26(b)(1)

As a general rule, "[f]or good cause, the court may order discovery of any matter relevant to the subject matter involved in the action. Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence." FED. R. CIV. P. 26(b)(1). Although relevant information need not be admissible at trial, courts refuse to order discovery if the information being sought is (1) irrelevant to the claim, or (2) protected by a recognized privilege. *Id.*; *see also Pearson v. Miller*, 211 F.3d 57, 65 (3d Cir. 2000). The precise boundaries of the Rule 26 relevance standard depend upon the context of each particular action, and the determination of relevance is within the discretion of the District Court. *See Barnes Found. v. Township of Lower Merion*, 1996 WL 653114, at *1 (E.D. Pa. Nov. 1, 1996). Notably however, the scope of discovery is not without its limits.

Teva alleges that MSD acquired the patent-in-suit by fraudulently concealing material prior art from the PTO and are therefore entitled to all privileged communications concerning MSD's allegedly fraudulent conduct in obtaining the '473 patent. (Defs.' Br. at 1.) Teva argues that they are "entitled to this relief (1) pursuant to the crime-fraud exception to the attorney-client privilege; and (2) because MSD has waived the privilege by injecting into issue the alleged good faith state of mind of those involved in the prosecution of the '473 patent." *Id.* MSD argues that the requested materials are protected as privileged because Teva's crime-fraud exception claim and waiver of the attorney-client privilege claim both fail. (Pl.'s Opp'n Br. at 2.) The documents sought by Teva are relevant because they are reasonably calculated to lead to admissible evidence pursuant to the Rule 26(b)(1) standard since said documents contain information that MSD

withheld from the PTO concerning the '473 patent. See FED. R. CIV. P. 26(b)(1).

B. Privileged Nature of Requested Documents

When a document is relevant to the subject matter of an action, the Court may order a party to produce it unless the document is protected by a recognized privilege. Fed. R. Civ. P. 26(b)(1). Communications between an attorney and client are protected by the attorney-client privilege. The purpose of this privilege is to promote frank discussions between a client and his/her attorney to allow the attorney to best represent the client. *Fisher v. United States*, 425 U.S. 391, 403, 96 S.Ct. 1569, 48 L. Ed. 2d 39 (1976). The privilege is not unconditional. It can be waived if the privileged information is communicated to outside parties. *U.S. v. Rockwell International*, 897 F.2d 1255, 1265 (3d Cir. 1990). Generally, when a party discloses privileged information to a third party, the privilege is extinguished, and the document is discoverable. *See in re Teleglobe Commc'n Corp.*, 493 F.3d 345, 364 (3d Cir. 2007).

It is clear that the attorney-client privilege attaches to the documents sought because neither Teva nor MSD dispute the privileged nature of the documents. The issue is whether Teva is entitled to the privileged communications concerning Plaintiff's allegedly fraudulent conduct in obtaining the '473 patent pursuant to the crime-fraud exception to the attorney-client privilege or because MSD has waived the privilege by injecting into issue the alleged good faith state of mind of those involved in the prosecution of the '473 patent.

C. Crime-fraud Exception

"A party seeking to compel testimony under the crime-fraud exception bears the initial burden of proving a prima facie case of crime or fraud before the attorney-client privilege is waived." *In re Impounded*, 241 F.3d 308, 317 (3d Cir. 2001). The elements of the crime-fraud

exception include:(1) a misrepresentation of a material fact; (2) intent to deceive; (3) justifiable reliance upon the misrepresentation by the party deceived; and (4) injury to the party deceived as a result of its reliance on the misrepresentation. *In re Spalding Sports Worldwide, Inc.*, 203 F.3d 800, 807 (Fed. Cir. 2000).

The Court concurs with MSD's contention that Teva bears the burden of proof of establishing the crime-fraud exception and has failed to satisfy the four elements of the crimefraud exception to the attorney-client privilege, does not justify production of the sought documents. See Pl.'s Opp'n Br. at 25. Teva fails to satisfy (1) a misrepresentation of a material fact, which is the first element of the crime-fraud exception because they only establish mere speculation of misrepresentation by MSD to the PTO. The next element of the crime-fraud is (2) intent to deceive, which Teva also fails to satisfy. MSD explains that "Teva's first contention—that Merck has not proven a lack of intent—is contrary to well-established law [because] [i]t is Teva that has the burden of proving intent, not the other way around." Id. at 19 (citing Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1365 (Fed. Cir. 2008)). MSD further explains that Teva's argument that MSD's patent attorney, Gabriel Lopez reviewed drafts of the Young publications, but did not disclose them to the PTO does not establish deceptive intent because said attorney reviewed the draft manuscripts to ensure that publication did not foreclose the patenting of future Merck LTD4 antagonists and "Merck had already decided that the information reflected in the model was innocuous enough to share with its direct competitors." See id. at 19-21. Moreover, Teva cites to a series of cases in which courts have invoked the crime-fraud exception because "the withheld information was material because it contradicted the arguments advanced by the patentee in support of patentability." (Teva's Letter

Dated October 29, 2008 ¶ 2). However, Teva fails to distinguish those cases from the one at bar by omitting the fact that the withheld information in the cited cases was known, while the withheld information at issue was unknown because inventors and MSD's patent attorneys testified that they do not remember seeing either of the Young publications during the prosecution of the patent at issue. Therefore, the withholding of unknown materials does not amount to an intent to deceive. The third element of the crime-fraud exception requires the moving party to establish (3) justifiable reliance upon the misrepresentation by the party deceived, and Teva fails to satisfy said element because Teva has not cited a single page of the more than 800 pages of prosecution history of the patent-in-suit nor any facts outside the prosecution history to support its contention that without MSD's non-disclosure the PTO would not have granted the patent-in-suit. *Id.* at 24. Lastly, Teva also fails to satisfy the final element of the crime-fraud exception, (4) injury to the party deceived as a result of its reliance on the misrepresentation because Teva fails to discuss any injury resulting from the alleged detrimental reliance of the PTO, therefore, any injury would be mere speculation. *Id.* at 25.

Furthermore, such failure does not justify an *in camera* review to establish Teva's claim that the crime-fraud exception applies even though a "lesser evidentiary showing is needed to trigger *in camera* review than is required to ultimately overcome the privilege," because some showing is still required. *United States v. Zolin*, 491 U.S. 554, 572 (1989). Accordingly, the Court denies the Motion to Compel on the grounds that the crime-fraud exception to the attorney-client privilege does not apply because Teva failed to establish the four elements of said exception.

D. Waiver of Attorney-Client Privilege Based Upon Fairness

Fairness is not a basis for waiver of the attorney-client privilege in the Third Circuit, despite Teva's argument that "[f]airness prevents a party from disclosing facts beneficial to its position while refusing to disclose, on the grounds of privilege, related facts adverse to its position." (Defs.' Br. at 22) (quoting *General Electric Co. v. Hoechst Celanese Corp.*, No. 87-458, 1990 U.S. Dist. LEXIS 14106, at *) In *Rhone-Poulenc Rorer Inc. v. Home Indemnity Co.*, 32 F.3d 851, 863-64 (3d Cir. 1994), the Third Circuit expressly rejected the "liberal" approach to waiver that is set forth in the cases relied upon by Teva. ("Relevance is not the standard for determining whether or not evidence should be protected from disclosure as privileged, and that remains the case even if one might conclude the facts to be disclosed are vital, highly probative, directly relevant or even go to the heart of an issue.) *Rhone-Poulenc*, 32 F.3d at 864.

Instead of following the liberal approach to waiver that Teva relies upon in its Motion, the Third Circuit adopted a more traditional approach to waiver: waiver only results when a party "attempts to prove a claim or defense by disclosing or describing an attorney client communication." *Id.* at 863. The Third Circuit further explained that "[a] party does not lose the privilege to protect attorney client communications from disclosure in discovery when his or her state of mind is put in issue in the action," even if the information is "vital, highly probative, directly relevant or even go[es] to the heart of an issue." *Id.* at 864.

The Court finds no waiver of the attorney-client privilege because Teva cites no Third Circuit authority that recognizes fairness as a grounds for waiver. Accordingly, the Court denies the Motion to Compel because it finds that MSD has not waived the privilege by injecting into issue the alleged good faith state of mind of those involved in the prosecution of the '473 patent.

E. Alternative Relief

Teva argues that if "the Court finds no waiver, then MSD should be precluded from offering alleged good faith explanations from those involved in the prosecution of the '473 patent for their non-disclosure of the Young LTD₄ receptor model." (Defs.' Br. at 26.) Specifically, Teva argues that MSD relied upon the inventors and prosecuting attorneys' testimony that they either consider the Young LTD₄ receptor model irrelevant to the prosecution of the '473 patent or were unaware of this prior art, while simultaneously asserting the attorney-client privilege over documents and communications that bear on the alleged subjective good faith of these witnesses. *Id.* at 25-26.

The attorney-client privilege cannot be used as both a sword and shield. *See Berckeley Inv. Group, Ltd. v. Colkitt*, 455 F.3d 195, 222 (3d. Cir. 2006); *see also Livingstone v. North Belle Vernon Borough*, 91 F.3d 515, 537 (3d Cir. 1996). Specifically, here, MSD cannot claim that all of their actions involving the PTO regarding the patent-in-suit were based upon good faith with respect to claiming that the non-disclosure of the Young LTD₄ receptor model was based upon either unawareness or concluding that it was not material, and then refuse to disclose documents and communications that bear on the alleged subjective good faith of these witnesses. However, MSD represented to the Court, on October 29, 2008, that an *in camera* review in unnecessary because no responsive privileged documents were found in Merck's privileged documents log. *See* MSD's Letter Dated October 29, 2008. The Court directed MSD to send any documents relating to the Young LTD₄ receptor model or the Young 88 and Young 89 publications to the Court for *in camera* review and they responded by stating that "Merck's outside counsel reviewed every document listed in Merck's privileged documents log. No responsive privileged

documents were found, and therefore, there are no documents to be produced for *in camera* review." *Id.* at \P 1. Accordingly, the Court denies the alternative relief sought as moot based alone upon the information in the October 29, 2008 MSD letter addressing the documents sought by the Court for *in camera* review.

III. CONCLUSION

For the reasons stated above, Plaintiff's Motion to Compel Production of all privileged communications concerning Plaintiff's allegedly fraudulent conduct in obtaining the '473 patent is on denied on the grounds that the crime-fraud exception does not apply. Alternatively, the Motion to Compel is denied on the grounds that there was no waiver of privilege. Finally, the alternative relief sought, specifically precluding MSD from offering alleged good faith explanations from those involved in the prosecution of the '473 patent for their non-disclosure of the Young LTD₄ receptor model is denied as moot based upon the fact that MSD's outside counsel found no responsive privileged documents in Merck's privileged documents log.

DATED: November 5, 2008